**PATENT** 

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Govindan RAJAMOHAN, et al Application No.: 10/814,850 Group No.: 1652

Filed: March 31, 2004 Examiner: Malgorzata A. Walicka

For: METHOD FOR OXYGEN REGULATED PRODUCTION OF RECOMBINANT

**STAPHYLOKINASE** 

Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

### STATEMENT OF RIOLOGICAL CULTURE DEPOSIT

	STATEMENT OF BIOLO	GICAL CU	LIURE DEPOSII
WARNIN	NG: Submission of a letter related to a biological reduction in patent term adjustment under 37 (		otice of Alolwance may subject an application to a 10). See Notice of May 29, 2001, 1247 OG 111-112,
_	June 26, 2001.	10	
I, _	CLIFFORD J. MAS		
	Name of Applicant or Assi	gnee or Assigne	e's representative
	CERTIFICATION UNDER 37		
	(When using Express Mail, the Ex		
	Express Mail cer	tification is opti	ional.)
I hereby	certify that, on the date shown below, this correspo	ndence is being:	
	MA	AILING	
⊠	deposited with the United States Postal Service in Box 1450, Alexandria, VA 22313-1450.	an envelope ado	dressed to the Commissioner for Patents, P. O.
	37 C.F.R. SECTION 1.8(a)		37 C.F.R. SECTION 1.10*
⊠	with sufficient postage as first class mail.		as "Express Mail Post Office to Address"  Mailing Label No (mandatory)
	TRAN	SMISSION	
	transmitted by facsimile to the Patent and Tradem	ark Office to (5'	71)-273-8200-
		Signa	ture
		$\mathcal{U}$	
Date: _	April 30, 2007	<u>CI</u>	LIFFORD J MASS
		(type o	or print name of person certifying)

\*WARNING:

Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. section 1.10(b).

"Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

hereby state:  1. That the following culture(s) referred to in the specif	fication of this application have been denosited	
1. That the following culture(s) referred to in the specin	neation of this application have been deposited	
pRM1	MTCC 5146	
Strain	Accession number	
pOXYSAK-1	MTCC 5147	
Strain	Accession number	
pOXYSAK-2	MTCC05148	
Strain	Accession number	
Strain	Accession number	
2. That the date of the above deposit is:		
(check appropriate ite	em below)	
<ul><li>[X] before the U.S. filing date of this application.</li><li>[] after the U.S. filing date of this application and protection the same culture(s) described in the application</li></ul>		
3. That the name and address of the depository is:		
MICROBIAL TYPE CULTURE COLLECTION AND C	GENE BANK INSTITUTE OF MICROBIAL	
TECHNOLOGY  Name of deposito	DIV	
·	•	
SECTOR 39-A, CHANDIGARH - 160 036, INDAI  Address of deposit	itory	
4. That a statement that the culture(s) deposited with the a was (were) capable of reproduction, if appropriate, on the executed by:		
(complete a, b or c	below)	
<ul><li>a. [X] the depository.</li><li>b. [ ] the applicant.</li><li>c. [ ] a competent third party.</li></ul>		

WARNING: If the applicant himself or a competent third party makes the statement that the microorganism is viable and is capable of reproduction, if appropriate, then the tests must have been performed on a sample certified to have been (1) received by the depository with the same samples actually deposited and (2) promptly returned to applicant.

5.	That,	with	respect	to the	permanence	of the	culture(s)	deposit:
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(complete a, b, or c)

- a. [X] the depository is an official depository, in accordance with the Budapest Treaty for the above deposited culture(s).
- b. [] the depository affords permanence of the deposit for at least 30 years or at least 5 years after the most recent storage request, whichever is longest.
- c. [] evidence that permanent availability of the microorganism is assured is provided in the form of the attached copy of the contract with the above-mentioned depository with respect to the deposited culture(s).

I state that should the microorganism(s) mutate, become nonviable or be inadvertently destroyed, applicants will replace such microorganism(s) for at least 30 years from the date of the original deposit, or at least 5 years from the date of the most recent request for release of a sample or for the life of any patent issued on the above-mentioned application, whichever period is longer.

- 6. That, with respect to availability of the culture(s), I state that the deposit has been made under conditions of assurance of (a) ready accessibility thereto by the public if a patent is granted whereby all restrictions to the availability to the public of the culture so deposited will be irrevocably removed upon the granting of the patent (M.P.E.P. 608.01 (p)), and (b) access to the culture will be available during pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. section 1.14 and 35 U.S.C. section 122.
  - [ ] Evidence of the accessibility of the culture(s) as set forth above is provided in the form of the attached copy of the contract with the above mentioned depository with respect to the deposited cultures.

April 30, 2007
Date

LADAS & PARRY LLP 26 WEST 61ST STREET NEW YORK, NEW YORK 10023 REG. NO.30,086(212)708-1890

P.O. Address of Signatory

CLIFFORD J. MASS
(type or print name of person signing)

Signature

<ul><li>[ ] Inventor</li><li>[ ] Assignee of complete interest</li><li>[X] Person authorized to sign on behalf of assignee</li></ul>				
(complete the following, if applicable)				
(type name of assignee)				
Address of assignee				
Title of person authorized to sign on behalf of assignee: Assignment recorded in PTO on Reel Frame				

A "STATEMENT UNDER 37 C.F.R. 3.73(b)" is attached.

# BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

### INTERNATIONAL FORM

To

Sri G.Rajamohan Scientist Institute of Microbial Technology Sector – 39A Chandigarh – 160 036. INDIA

\* Form MTCC BP/4 (sole page)

NAME AND ADDRESS OF THE DEPOSITOR

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT issued pursuant to Rule 7.1 by the INTERNATIONAL DEPOSITARY AUTHORITY Identified at the bottom of this page

dentification reference given by the DEPOSITOR:	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:
E.coli pRM1	MTCC 5146
II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED	TAXONOMIC DESIGNATION
The microorganism identified under I above was accompanied	d by:
a scientific description	
() a proposed taxonomic designation	
(Mark with a cross where applicable)	**
III. RECEIPT AND ACCEPTANCE	·
This International Depositary Authority accepts the microorg	anism identified under Fabove,
which was received by it on	(date of the original deposit)
IV. RECEIPT OF REQUEST FOR CONVERSION	
The microorganism identified under I above was received by	this International Depositary
Authority on 19.03.2002 (date of	the original deposit) and a request to convert the original
deposit under the Budapest Treaty was received by it on2	5.03.2004 (date of receipt of request for conversion)
V. INTERNATIONAL DEPOSITARY AUTHORITY	
Name: Dr. G.S.PRASAD	MTCC-an IDA 95MLS
Address: Microbial Type Culture Collection & Gene Bank Institute of Microbial Technology Sector 39-A, Chandigarh - 160 036	Institute of Microbial Technology
India	Date: 30.03.2004

### BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

### INTERNATIONAL FORM

To

Sri G.Rajamohan Scientist Institute of Microbial Technology Sector – 39A Chandigarh – 160 036. INDIA

NAME AND ADDRESS OF THE PARTY TO WHOM THE VIABILITY STATEMENT IS ISSUED VIABILITY STATEMENT issued pursuant to Rule 10.2 by the INTERNATIONAL DEPOSITARY AUTHORITY Identified on the following page

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
Name: Sri G.Rajamohan Address: Scientist Institute of Microbial Technology Sector – 39A Chandiagth – 160 036 INDIA	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY  MTCC 5146  Date of the deposit or of the transfer:  30-03-2004

III. VIABILITY STATEMENT	
The viability of the microorganism identified under II a	bove was tested
on 29.03.2004	<sup>3</sup> on that date, the said microorganism was
(X) viable	
() <sup>3</sup> no longer viable	

- Indicate the date of the original deposit or, where the new deposit or a transfer has been made, the most recent relevant date (date of the new deposit or date of the transfer).
- <sup>2</sup> In the cases referred to in Rule 10.2(a)(ii) and (iii), refer to the most recent viability test.
- <sup>3</sup> Mark with a cross the applicable box

<sup>\*</sup> Form MTCC BP/9 (first page)

# V. INTERNATIONAL DEPOSITARY AUTHORITY Name: Dr. G.S. PRASAD Microbial Type Culture & Gene Bank Address: Institute of Microbial Technology Sector 39-A, Chandigarh - 160 036 India N. INTERNATIONAL DEPOSITARY AUTHORITY Signature of Coord hand the power to represent the International Microbial Type Culture & Gene Bank Address: Institute of Microbial Technology Sector 39-A, Chandigarh - 160 036 India Date: 30.03.2004

<sup>&</sup>lt;sup>4</sup> Fill in if the information has been requested and if the results of the test were negative.

<sup>†</sup> Form MTCC BP/9 (second and last page)

### BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

### INTERNATIONAL FORM

Sri G.Rajamohan Scientist Institute of Microbial Technology Sector - 39A Chandigarh - 160 036. INDIA

\* Form MTCC BP/4 (sole page)

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT issued pursuant to Rule 7.1 by the
INTERNATIONAL DEPOSITARY AUTHORITY
Identified at the bottom of this page

NAME AND ADDRESS OF THE DEPOSITOR	
DENTIFICATION OF THE MICROORGANISM	
dentification reference given by the DEPOSITOR:	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:
E.coli pOXYSAK1	MTCC 5147
I. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAX	KONOMIC DESIGNATION
he microorganism identified under I above was accompanied by	:
X) a scientific description	
) a proposed taxonomic designation	
Mark with a cross where applicable)	~ <u>~</u>
II. RECEIPT AND ACCEPTANCE	
his International Depositary Authority accepts the microorganism	n identified under I above,
which was received by it on	(date of the original deposit) <sup>1</sup>
V. RECEIPT OF REQUEST FOR CONVERSION	
The microorganism identified under I above was received by this	International Depositary
Authority on 19.03,2002 (date of the c	original deposit) and a request to convert the original
deposit under the Budapest Treaty was received by it on 25.03	(date of receipt of request for conversion)
v. International depositary authority	
Name: Dr. G.S.PRASAD	· G5/W-5
Address:	
Microbial Type Culture Collection & Gene Bank	Signatured of personal flat the power to represent the International title international statement of the control of the contr
Institute of Microbial Technology	Sector 39-A, Chandigarh-160 036
Sector 39-A, Chandigarh - 160 036 India	Date: [NDIA 30.03.2004-

### BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

### INTERNATIONAL FORM

To

Sri G.Rajamohan
Scientist
Institute of Microbial Technology
Sector – 39A
Chandigarh – 160 036. INDIA

NAME AND ADDRESS OF THE PARTY TO WHOM THE VIABILITY STATEMENT IS ISSUED VIABILITY STATEMENT issued pursuant to Rule 10.2 by the INTERNATIONAL DEPOSITARY AUTHORITY Identified on the following page

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
Name: Sri G.Rajamohan Address:	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY MTCC 5147
Scientist Institute of Microbial Technology Sector – 39A Chandigarh – 160 036, INDIA	Date of the deposit or of the transfer:

III. VIABILITY STATEMENT	
The viability of the microorganism identified under II above was tested	
on <u>29.03.2004</u>	<sup>2</sup> on that date, the said microorganism was
(X) viable	
()³ no longer viable	

- Indicate the date of the original deposit or, where the new deposit or a transfer has been made, the most recent relevant date (date of the new deposit or date of the transfer).
- 2 In the cases referred to in Rule 10.2(a)(ii) and (iii), refer to the most recent viability test.
- Mark with a cross the applicable box

<sup>\*</sup> Form MTCC BP/9 (first page)

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED		
V. INTERNATIONAL DEPOSITARY AUTHORITY		
Name:		
	95/hl-5	
Dr. G.S. PRASAD	MTCC on IDA	
Microbial Type Culture & Gene Bank	Signature(4) of County law in the power to represent the	
Address:	International Process of the Process	
Institute of Microbial Technology	INDIA	
Sector 39-A, Chandigarh - 160 036	Date: 30.03.2004	
India		

<sup>&</sup>lt;sup>4</sup> Fill in if the information has been requested and if the results of the test were negative.

<sup>†</sup> Form MTCC BP/9 (second and last page)

## BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

### INTERNATIONAL FORM

Sri G.Rajamohan Scientist Institute of Microbial Technology Sector – 39A Chandigarh – 160 036. INDIA

NAME AND ADDRESS OF THE PARTY TO WHOM THE VIABILITY STATEMENT IS ISSUED

VIABILITY STATEMENT issued pursuant to Rule 10.2 by the INTERNATIONAL DEPOSITARY AUTHORITY Identified on the following page

I. DEPOSITOR	IL IDENTIFICATION OF THE MICROORGANISM
Name:	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY
Sri G.Rajamohan	MTCC 5148
Scientist Institute of Microbial Technology	Date of the deposit or of the transfer:
Sector – 39A	30-03-2004

III. VIABILITY STATEMENT	
The viability of the microorganism identified under II above was tested	
on <u>29.03.2004</u>	<sup>2</sup> on that date, the said microorganism was
(X) viable	•
()³ no longer viable	

Indicate the date of the original deposit or, where the new deposit or a transfer has been made, the most recent relevant date (date of the new deposit or date of the transfer).

<sup>&</sup>lt;sup>2</sup> In the cases referred to in Rule 10.2(a)(ii) and (iii), refer to the most recent viability test.

<sup>3</sup> Mark with a cross the applicable box

<sup>\*</sup> Form MTCC BP/9 (first page)

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED		
V. INTERNATIONAL DEPOSITARY AUTHORITY		
Name:	aspl-5	
Dr. G.S. PRASAD		
Microbial Type Culture & Gene Bank  Address: Institute of Microbial Technology Sector 39-A, Chandigarh - 160 036 India	SignanuM) of Googy pality the power to represent the International Depositary, Authority, or of authorised official (1) Stitute of Microbial Technology Sector 39-A, Chandigarh-150 036 INDIA  Date: 30.03.2004	

Fill in if the information has been requested and if the results of the test were negative.

<sup>&</sup>lt;sup>†</sup> Form MTCC BP/9 (second and last page)